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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,978	10/06/2000	Jing Min	5796-01-MJA	7511
28523	7590	11/12/2003	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			CARLSON, KAREN C	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 11/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/647,978	Applicant(s) MIN ET AL.	
	Examiner Karen Cochran Carlson, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 6) <input type="checkbox"/> Other: _____ |

Applicant's election with traverse of Invention V, Claims 12 and new Claims 21-26, in the paper filed July 25, 2003 is acknowledged. The traversal is on the ground(s) that Claim 13 should be examined with Invention V, Claim 12 and 21-26 because Claim 13 is drawn to determining ligand for SYNIP and Claim 12 is drawn to determining compounds which interfere with the interaction of SYNIP and a determined ligand. This is not found persuasive because these methods are different in concept and in compound and therefore these two inventions are patentably distinct for reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-26 are currently pending. Claim 1-11 and 13-20 have been withdrawn from further consideration by the Examiner because these claims are drawn to non-elected inventions. Claims 12 and 21-26 are currently under examination.

Priority is set to April 19, 1998.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear in Claim 12 what is meant by "SYNIP". At page 2 of the specification, "SYNIP" is specifically defined as the acronym for syntaxin-4 interacting protein. Yet at page 12, para. 1, of the specification, "SYNIP" is broadly defined as not only being naturally occurring SYNIPs (syntaxin-4 interacting protein) but also functional derivatives and variants of SYNIPs. A

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"functional derivative" is defined as any compound having a qualitative biological activity in common with a native SYNIP, such as the ability to bind to syntaxin-4 or other cognate ligands. What other "cognate ligands" are included in this definition? Indeed, at the last sentence of page 12, para. 1, the functional derivative can include peptides and small organic molecules having qualitative biological activity. "Derivative" (and variants) is further defined as amino acid and glycosylation variants, as well as covalent modifications of SYNIP. Therefore, the functional derivatives and variants that are included in the definition of "SYNIP" need not have a common structure with SYNIP, or even bind to syntaxin-4. The definition of "SYNIP" at page 12 is so broad as to be meaningless because there is no definite structure and no definite function set forth.

Claim 12 is not clear because the term "syntaxin-4" is defined as including but not limited to syntaxin-4 and the like. What is "and the like"?

It is not clear in Claim 12 what is meant by the phrase "interferes with the interaction". At page 6, para. 3, of the specification, the term "interaction" is stated to include but is not limited to binding, affecting, and regulating. Thus, it is not clear how a compound interferes with the effect of SYNIP and syntaxin-4, or interferes with the regulation of SYNIP and syntaxin-4.

In each of Claims 21, 23, and 24, it is not clear what a polypeptide would look like if it had an amino acid "substantially similar" to SEQ ID NO: 2 or SEQ ID NO: 5.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12 and 21-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to describe SYNIPs as defined on page 12, para. 1. Specifically, the specification defines "SYNIP" broadly as not only being naturally occurring SYNIPs (syntaxin-4 interacting protein) but also functional derivatives and variants of SYNIPs. A "functional derivative" is defined as any compound, peptides, or small organic molecules having a qualitative biological activity in common with a native SYNIP, such as the ability to bind to syntaxin-4 or other cognate ligands. The specification does not describe any compound, peptides, or small organic molecules having a qualitative biological activity in common with a native SYNIP (syntaxin-4 interacting protein) and having the ability to bind to syntaxin-4. The specification does not describe any other "cognate ligands" that bind to SYNIP (syntaxin-4 interacting protein). The specification does not describe any "derivative" (an variants) that are amino acid and glycosylation variants of SYNIP, as well as covalent modifications of SYNIP. Therefore, The specification does not describe functional derivatives and variants that that are included in the definition of "SYNIP", which need not have a common structure with SYNIP, or even bind to syntaxin-4.

The specification does not describe syntaxin-4 like compounds, wherein syntaxin-4 is defined as being syntaxin-4 "and the like".

The specification does not describe any compound that "interferes with the interaction" of SYNIP and syntaxin-4, or how this interference would be assessed. At page 6, para. 3, of the specification, the term "interaction" is stated to include but is not limited to binding, affecting, and regulating. Thus, the specification does not teach how to assay for a compound that interferes with the affect of SYNIP and syntaxin-4, or interferes with the regulation of SYNIP and syntaxin-4.

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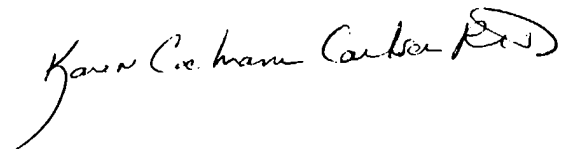
The specification does not teach polypeptide that are "substantially similar" to SEQ ID NO: 2 or SEQ ID NO: 5 and having function.

Thus, the specification lacks written description of the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. Upon the move of the PTO to Alexandria, VA in January, 2003, the telephone number will be 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER